REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated March 11, 2003.

Applicants have above amended the Specification to claim priority and make cross-reference to related and copending provisional application 60/188,957 filed March 13, 2000, an application on which the instant Application and its related predecessor application (U.S. Serial No. 09/632,131, filed August 3, 2000 (of which the instant Application is a continuation-in-part) are based. The cross reference to this provisional application was inadvertently omitted at the time of filing of the instant application and the earlier filed application U.S. Serial No. 09/632,131 and the delay in providing this cross reference was unintentional.

The Examiner has objected to the specification because of various informalities. The Examiner notes that the description of Figures 1 and 2, while describing parts A and B do not refer to these figure parts the same as Figures 5-11 in which each Description of a figure begins such as "Figure 6A-B" or as "Figure 7 A and B". The Examiner suggests that consistency be maintained. Applicants have above amended the Specification to provide consistency and refer in the figures in the style of "Figure 7A and B". Applicants have therefore above amended the Specification in its description of Figures 1, 5, 6, 15 and 19 for consistency.

The Examiner additionally remarks that certain portions of the Specification list sequences which appear to meet the definition for an amino acid sequence but do not have an associated SEQ ID No:, specifically at page 4, line 20 and at page 21, line 10. These have above been amended to make reference to the appropriate SEQ ID NO:

Replacement paragraphs for all of the indicated changes are set forth above, and entry and favorable consideration thereof is requested.

Status of the Claims and Claim Objections

Claims 4, 5 and 14-17 are pending in the application. Claims 1-3, 6-13 and 18-48, which are withdrawn from consideration, have been canceled. Claims 4, 14 and 16 have been

amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification.

The Examiner has objected to Claims 4, 5 and 14-17 as including non-elected subject matter. Applicants have above amended Claims 4, 14 and 16 to refer to the elected subject matter, specifically the Homo sapiens heart alpha kinase nucleic acid.

Particularity and Distinctiveness of the Claims

The Examiner has rejected Claims 4, 5 and 14-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner rejects Claim 16 as indefinite in the recitation of part j. Applicants have above amended Claim 16 to recite "DNA sequences that encode an amino acid sequence" as suggested by the Examiner.

Claim 4 (and its dependent claims 5, 14 and 15) are rejected as indefinite in the recitation of a heart alpha kinase, the Examiner asserting that it is unclear what features define a heart alpha kinase. Applicants respectfully disagree and submit that the term heart alpha kinase is clear to the skilled artisan, based on a reading of the pending claims and the description and definition provided in the Specification. The Examiner points to pages 5 and 26 which provide the characteristics of an alpha kinase and the term heart alpha kinase. In addition, the Specification, including at pages 76 and 83 characterizes and defines heart alpha kinase as a protein predominantly expressed in the heart and as a large protein of more than 1000 amino acids with a typical alpha-kinase catalytic domain located at the C-terminus. Additional description and characterization of heart alpha kinase is provided at pages 83 to 85, which discusses sequence characteristics and tissue distribution. Taken together, the Specification and claims provide a clear definition of what features define a heart alpha kinase.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, second paragraph, is obviated and should be withdrawn.

The Specification Fully Enables the Claimed Invention

The Examiner has rejected Claims 16 and 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the Application was filed, had possession of the claimed invention. The Examiner states that Claims 16 and 17 are directed to a genus of unicellular host cells transformed with any DNA which encodes any alpha kinase or a fragment thereof, wherein said DNA will hybridize to SEQ ID NO: 34 under standard stringency conditions, and asserts that the Specification does not contain any disclosure of the structure and function of all DNA sequences encompassed by the genus of the claims. Applicants respectfully disagree. Claims 16 and 17 are directed to unicellular host cells transformed with DNA encoding a heart alpha kinase, wherein said DNA consists of the DNA of SEQ ID NO: 34, DNA sequences hybridizing thereto under standard stringency hybridization conditions, and DNA sequences that encode the same amino acid sequence of SEQ ID NO: 34 or its hybridizing sequences. These DNAs are structurally and functionally related as heart alpha kinases, as defined in the Specification (and as noted above). Heart alpha kinase sequences from two distinct species, human and mouse, are provided in the Specification and the sequences in the claimed host cells must hybridize to or encode the disclosed sequences. Applicants submit that the unicellular host cells of pending Claims 16 and 17 are described in the Specification in such a way as to reasonably convey to the skilled artisan that the inventor had possession thereof at the time the Application was filed.

The Examiner has further rejected Claims 16 and 17 under 35 U.S.C. 112, first paragraph, because the Examiner asserts that the Specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner remarks that the Specification, while being enabling for a host cell transformed with a DNA molecule comprising SEQ ID NO: 34, does not reasonably provide enablement for any host cell transformed with any DNA sequence which encodes a fragment of a DNA sequence which encodes SEQ ID NO: 34. The Examiner further suggests that it would require undue experimentation for one skilled in the art to arrive at the majority of those host cells of the

claimed genus comprising the DNA sequence. Applicants respectfully disagree and submit that the Specification clearly enables the skilled artisan to make and/or use the host cells as claimed.

While some experimentation to make, test and use such host cells would be necessary, such experimentation would utilize well known methods and standard skills and would not constitute undue experimentation. With regard to the determination of what is undue experimentation, the PTO and the courts have commented that "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." MPEP § 2164.01, *citing M.I.T. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). The test of enablement is not whether experimentation is necessary, but whether or not it is undue. *Ibid, citing In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). With regard to this rejection, the Examiner points to the Wands factors, which are to be considered in determining undue experimentation. *Ibid, citing In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In the present instance: (1) the quantity of experimentation, while significant, is not undue for the skilled artisan; (2) the direction or guidance provided by the specification is sufficient for the skilled artisan and appropriate for the time; (3) working examples from two distinct species, specifically human and mouse, are provided; (4) the nature of the invention, including, but not limited to the disclosure of human and mouse heart alpha kinase sequences (5) the extent of prior art available to those skilled in the art with regard to making and testing host cells was very significant at the time of filing; (6) the relative skill of those in the art is substantial - the courts have determined that, in molecular biology, the level of skill in the art corresponds to that of a Ph.D. with postdoctoral experience; (7) the making, testing and use of the host cells is certainly not unpredictable; and (8) the breadth of the claims is commensurate with the significant skill of those in the art. In view of the foregoing, Applicants submit that given the guidance provided by the specification, the well known criteria or parameters for making and testing of host cells, and the significant level of skill in the art a person of ordinary skill in the art could, without undue experimentation, make and use the host cells encompassed by the claims.

In view of the foregoing remarks, Applicants submit that the Examiner's rejection

under 35 U.S.C. 112, first paragraph may properly be withdrawn.

The §102 Rejection

Claims 16 and 17 have been rejected under 35 U.S.C. 102 (a) as being anticipated by Scharenberg et al [WO 00/40614, July 2000]. Scharenberg teach nucleic acids encoding a protein named SOC-2/CraC-1 with kinase activity and homology to the TRP family of calcium channels. The Examiner asserts that the nucleic acids of Scharenberg are clearly encompassed by DNA which encodes a fragment of an alpha kinase. Applicants respectfully disagree. Anticipation is a question of fact. As defined by the Federal Circuit, "[t]o anticipate a claim a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject-matter." *PPG Industries, Inc. vs Guardian Industries Corp., 37 USPQ2d 1618 (Fed. Cir. 1996) (emphasis added).* Scharenberg neither discloses every element of the rejected claims nor enables one skilled in the art to isolate or make the anticipating subject matter, specifically the claimed host cells. Applicants submit that the sequence of the SOC-2/CraC-1 kinase, which is a completely different sequence from the heart alpha kinase sequence, does not anticipate per se the claimed host cells transformed with heart alpha kinase. Scharenberg does not disclose or even suggest the particular alpha kinase sequences of the instant Application, including the heart alpha kinase, and further does not disclose or suggest the host cells transformed with heart alpha kinase sequence. Applicants assert that the claimed host cells of the present invention are transformed with nucleic aciid which is absolutely distinct from the nucleic acid of Scharenberg and are not anticipated by Scharenberg.

In view of the foregoing remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 102(a) may properly be withdrawn.

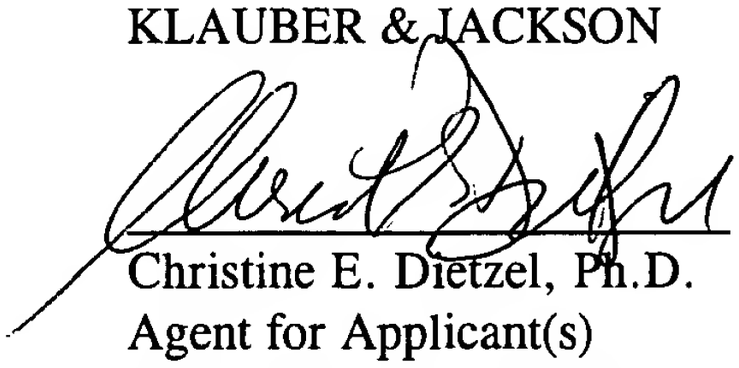
CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the

file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON



Christine E. Dietzel, Ph.D.
Agent for Applicant(s)
Registration No. 37,309

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack NJ 07601
Tel: (201) 487-5800